UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALKERMES, INC. and ALKERMES PHARMA IRELAND LIMITED, *Plaintiffs*, v. TEVA PHARMACEUTICALS USA, INC., *Defendant*.	Civil Action No. 20-12470 (MCA)(MAH) *Filed Electronically*

TEVA'S MOTION *IN LIMINE* NO. 1 TO PRECLUDE ALKERMES FROM PROVIDING EVIDENCE OR TESTIMONY, OR OTHERWISE REFERENCING, TEVA'S PURPORTED ROLE IN THE OPIOID EPIDEMIC

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Teva respectfully requests the Court, pursuant to Fed. R. Evid. 401, 402 and 403, preclude Alkermes from introducing at trial evidence regarding Teva's opioids, Teva's purported role in "fueling" the opioid epidemic, and jury verdicts and other lawsuits regarding these issues as this evidence is wholly irrelevant to the sole issue of validity of Alkermes's '499 patent, but is highly prejudicial to Teva and a waste of the parties and this Court's time during trial.

During the January 20, 2022 deposition of Teva's corporate witness, Lina Lahoz, Alkermes extensively questioned Ms. Lahoz regarding Teva's sale of its prescription opioids, as well as a 2021 state court jury verdict and other then-pending (now settled) lawsuits regarding these sales, including whether such evidence showed that Teva helped to "fuel[] opioid addiction" and was "involv[ed] in the opioid epidemic." Ex. A[1] (Lahoz Tr.) at 108:21-114:15; *see also id.* at 99:16-108:6. Alkermes intends to assert (or at least heavily imply) at trial that Teva, did in fact, "fuel" the opioid epidemic, as Alkermes has not only designated Ms. Lahoz's deposition testimony, but also cited a myriad of documents and exhibits in its pretrial disclosures regarding Teva's prescription opiates and these lawsuits.[2] D.I. 160 at Exhibit A, p. 5-7 (designating Ms. Lahoz's testimony); *id.* at 22, FN. 11 (Alkermes's Contested Facts, citing a July 2022 article regarding Teva's settlement of opioid-related lawsuits); *id.* at Exhibit C, p. 11, 20 (listing PTX-146, PTX-148, and PTX-265, which are news articles and webpages regarding Teva's opioids and related lawsuits). This evidence is entirely irrelevant, highly improper, and prejudicial to Teva, and Teva respectfully submits it should be precluded.

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[1] "Ex. __" refers to exhibits to the Declaration of Christina Dashe, filed concurrently herewith.

[2] In fact, in order to avoid filing a needless motion *in limine* to preclude such plainly irrelevant and prejudicial evidence, Teva recently inquired whether Alkermes actually intended to proffer this evidence at trial, but Alkermes refused to confirm that it would not.

As an initial matter, Teva vehemently denies Alkermes's inflammatory allegations and implications of culpability for the national tragedy of the opioid epidemic. However, Teva should not have to spend time and resources during trial defending itself against these false allegations because the question of whether or to what extent Teva is responsible for the opioid epidemic is not relevant to any claim or defense in this case. This is a *patent* case relating only to whether: (a) the long-acting naltrexone formulation and its purportedly unique AUC properties recited in the asserted claims of Alkermes's '499 patent were obvious to a POSA in view of the prior art; and (b) whether the asserted claims are further invalid for failing to satisfy the statutory requirements of 35 U.S.C. § 112. Thus, evidence regarding Teva's alleged sales of unrelated prescription opioids and the subsequent lawsuits that do not involve the asserted '499 patent have no probative value or relevance to the sole issue of validity of the '499 patent, and should be excluded. *See Evolved Wireless, LLC v. Apple Inc.*, No. CV 15-542-JFB-SRF, 2019 WL 1100471, at *1 (D. Del. Mar. 7, 2019) (in a patent suit, excluding allegations of unrelated misconduct by the accused infringer as irrelevant and unfairly prejudicial); *see also In re Biogen '755 Patent Litigation*, No. 10-2734 (CCC)(JBC), 2018 WL 3613162, at *1 (D.N.J. July 26, 2018) ("[t]he purpose of a *motion in limine* is to bar irrelevant, inadmissible, and prejudicial issues from being introduced at trial, thus narrow[ing] the evidentiary issues for trial") (internal citations and quotations omitted).

Moreover, Teva has not cited or relied upon the sale or use of its own opioids or these lawsuits in this litigation, including in its contentions regarding invalidity, and Teva likewise stipulated to infringement of the '499 patent. Thus, evidence regarding *Teva's* alleged conduct concerning the opioid epidemic is irrelevant to the sole issue of the validity of *Alkermes's* patent. *See* D.I. 58. Indeed, Alkermes did not cite any evidence regarding Teva's opioid sales or lawsuits

in its own validity contentions, discovery responses, or expert reports, evidencing the lack of relevance of this evidence to the issues for trial.

Alkermes's *only* proffered justification for offering this evidence is that it is relevant to the issue of non-obviousness because, according to Alkermes, "Teva marketed prescription opioids, and thus had information relating to the demand for and long-felt need for Vivitrol." *See* D.I. 160 at 22, FN. 11 (Alkermes's Contested Facts). For starters, because Alkermes included this bare assertion for the first time in its portions of the parties' recent proposed final pretrial order, Alkermes's assertion should be excluded for the separate reason that Alkermes failed to timely disclose this theory in its contentions or during discovery. *Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, No. CIV. 12-3289 PGS LHG, 2014 WL 997532, at *9 (D.N.J. Jan. 6, 2014) (striking new, improperly disclosed invalidity evidence); *Celgene Corp. v. Hetero Labs Ltd.*, No. 17-3159 (ES)(MAH), 2021 WL 3701700, at *2 (D.N.J. June 15, 2021) (the Local Patent Rules "are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed," and so parties may not rely upon theories that were not properly disclosed).

Moreover, Alkermes's theory of relevance is unavailing. First, for this evidence to be at all probative of non-obviousness, it must be tied to the merits of the claimed invention. *See In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011). Yet Teva's sale of unrelated prescription opioids and lawsuits stemming from such sales have absolutely nothing to do with whether there was "demand for and long-felt need for" the purportedly unique AUC properties flowing from administration of the claimed formulation.[3]

[3] Ms. Lahoz's own testimony also contradicts Alkermes's assertion that Teva had knowledge of demand or need for Vivitrol or a later generic, since she testified that she was not aware of Teva

Second, even if the opioid evidence is somehow relevant (it is not), it still does not support Alkermes's contentions of long-felt need since the need is evaluated only through to the filing date of the asserted patent. *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989, 998 (Fed. Circ. 2009); *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009). Yet Alkermes has not produced or cited any evidence showing that Teva's actions selling prescription opioids occurred during the relevant time period *before* the '499 patent application's April 22, 2004 filing date. Indeed, the news articles and other evidence cited by Alkermes regarding Teva's opioids and related lawsuits are dated between 2020 and 2022, and do not contain any mention of activities occurring *before* April 22, 2004. *See, e.g.*, Ex. B (PTX-146) (screen grab of Teva's website listing its prescription opioids dated 2020); Ex. C (PTX-148) (news article dated 2021 and referring to jury verdict from that year), Ex. D (PTX-265) (news article dated 2022 and referring to settlements dated that year). Thus, the evidence Alkermes intends to seek to offer at trial regarding Teva's actions and purported awareness of the opioid epidemic *more than a decade after* 2004 is irrelevant to whether there was a long-felt need that was solved by the claimed invention as of the 2004 filing date. Nor has Alkermes identified any other validity issue to which such evidence might be relevant, because it cannot.

Further, even if the Court finds that the evidence Alkermes has cited regarding Teva's sale of prescription opioids, related lawsuits, and alleged awareness of and culpability for the opioid epidemic has some probative value (it does not), this evidence is facially inflammatory and is not at all necessary for Alkermes to show there was any sort of need or demand for Vivitrol. Nor is it necessary to rebut *any* of Teva's assertions of invalidity. Courts routinely

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considering the opioid epidemic when deciding whether to seek approval of its accused ANDA product. Ex. A (Lahoz Tr.) at 102:15-103:8.

exclude precisely such evidence due to the risk of unfair prejudice and waste of time, and the same result should apply here. *See, e.g.*, *MF Global Holdings Ltd. v. PricewaterhouseCoopers LLP*, 232 F. Supp. 3d 558, 570 (S.D.N.Y. 2017) ("courts often prohibit the use of certain 'pejorative terms when such categorizations were inflammatory and unnecessary to prove a claim'"); *Finjan, Inc. v. Blue Coat Sys., Inc.*, No. 13-cv-03999-BLF, 2015 WL 4129193, at *2 n. 1 (N.D. Cal. July 8, 2015) (similar); *Grace v. Apple, Inc.*, No. 17-CV-00551-LHK, 2020 WL 227404, at *1–2 (N.D. Cal. Jan. 15, 2020) (excluding evidence regarding prior lawsuits and verdicts involving the defendant that "in no way dictate the outcome of this action" because such evidence was "of minimum probative value," "would likely have a significant improper influence," and would "'. . . likely [] give rise to time-consuming tangents about the merits of those trials'").

Accordingly, because evidence regarding Teva's opioids, Teva's purported role in "fueling" the opioid epidemic, and jury verdicts and other lawsuits regarding these issues are entirely irrelevant to any issue in this case, and because its total lack of probative value is heavily outweighed by risk of unfair prejudice and waste of time, Teva respectfully submits this evidence should be excluded pursuant to Fed. R. Evid. 401, 402, and 403.

Dated: September 29, 2022

s/Liza M. Walsh

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